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SUPREME COURT

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STATE OF MICHIGAN

IN THE SUPREME COURT

(ON APPEAL FROM THE MICHIGAN COURT OF APPEALS)
(Collins, P.J. (not participating), and Murphy and Jansen, JJ.)

AMARA TAYLOR and LEE ANN RINTZ,

Plaintiffs-Appellees,

Supreme Court No. 120653

Court of Appeals No. 217269
Wayne County Circuit Court
Case No. 97-731636-NP
Hon. Marianne O. Battani

.H. ROBINS COMPANY, INCORPORATED, /YETH-AYERST LABORATORIES COMPANY ıd AMERICAN HOME PRODUCTS ORPORATION,

Defendants-Appellants,

ıd

ATE PHARMACEUTICALS, SMITHKLINE EECHAM CORPORATION, ZENITH GOLDLINE HARMACEUTICALS, INC., ABANA HARMACEUTICALS, INC., RICHWOOD HARMACEUTICAL COMPANY, INC., ION ABORATORIES, INC., MEDEVA HARMACEUTICALS, INC., INTERNEURON HARMACEUTICALS, INC., CAMALL COMPANY, ABORATORIES SERVIER and ALL MICHIGAN HYSICIANS WHO PRESCRIBED OR GAVE EN-PHEN AND/OR REDUX TO MICHIGAN 'ATIENTS,

Defendants.

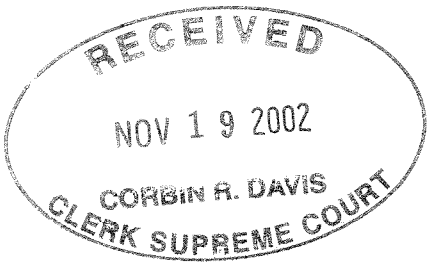
ıd

JDITH H. ROBARDS and KENNETH W. ROBARDS,

Plaintiffs-Appellees,

Supreme Court No. 120654

DEFENDANTS-APPELLANTS AMERICAN HOME PRODUCTS CORPORATION, A.H. ROBINS COMPANY, INCORPORATED AND WYETH-AYERST LABORATORIES COMPANY'S BRIEF IN REPLY TO PLAINTIFFS-APPELLEES' COMBINED BRIEF ON APPEAL



.H. ROBINS COMPANY, INCORPORATED,
/YETH-AYERST LABORATORIES COMPANY
id AMERICAN HOME PRODUCTS
ORPORATION,

Defendants-Appellants,

Court of Appeals No. 227700
Washtenaw County Circuit Court
Case No. 99-5373-MN
Hon. David S. Swartz

)YCE KAFERLE, M.D., and EVELYN ECCLES, M.D.,
ATE PHARMACEUTICALS, SMITHKLINE
EECHAM CORPORATION, ZENITH
OLDLINE PHARMACEUTICALS, INC.,
BANA PHARMACEUTICALS, INC.,
ICHWOOD PHARMACEUTICAL COMPANY,
)N LABORATORIES, INC., MEDEVA
HARMACEUTICALS, INC., PARMED
HARMACEUTICALS, INC., EON LABS
IANUFACTURING, INC., and LES
ABORATORIES SERVIER,

Defendants.
_____/

DEFENDANTS-APPELLANTS AMERICAN HOME PRODUCTS CORPORATION, A.H. ROBINS COMPANY, INCORPORATED AND WYETH-AYERST LABORATORIES COMPANY'S BRIEF IN REPLY TO PLAINTIFFS-APPELLEES' COMBINED BRIEF ON APPEAL

ORAL ARGUMENT REQUESTED

PROOF OF SERVICE

HONIGMAN MILLER SCHWARTZ AND COHN
Attorneys for Defendants-Appellants
By: Ronald S. Longhofer (P-25580)
Andrew Doctoroff (P-44344)
2290 First National Building
Detroit, Michigan 48226-3583
(313) 465-7000

(see signature page for additional involved attorneys)

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I. INTRODUCTION

Plaintiffs-Appellees' Combined Brief on Appeal ("Plaintiffs' Brief") fails to respond in ny way to the dispositive legal issues set forth in the Brief on Appeal filed by Wyeth,[1] articularly the authorities demonstrating that, in enacting MCL § 600.2946(5); MSA § 7A.2946(5) (hereinafter, "Section 2946(5)"), the Michigan Legislature **exercised** legislative uthority rather than delegated it. Nor do Plaintiffs respond to any of the numerous arguments lemonstrating that the Court of Appeals' decision-making was deeply flawed. Instead, while laintiffs expressly recognize that arguments addressed to the policy choices made by the egislature should have no bearing on the sole issue before this Court,[2] Plaintiffs' Brief focuses n unsupported anti-Food and Drug Administration ("FDA") rhetoric and arguments directed to he wisdom of the legislation. The few other arguments Plaintiffs make in support of their ontention that Section 2946(5) is unconstitutional do not withstand careful scrutiny and, in one nstance, are based on a brazen factual misrepresentation.

For the reasons stated below, and in Wyeth's Brief on Appeal, the Court should reverse he decision of the Court of Appeals, declare Section 2946(5) to be constitutional, and hold that laintiffs' claims fail as a matter of law because, as Plaintiffs have conceded, they are barred by he statute.

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[1]On August 3, 1998, A.H. Robins Company Incorporated merged with American Home roducts Corporation ("AHPC") and ceased to exist as a separate entity. The name of AHPC hanged to "Wyeth" on March 11, 2002. For ease of reference, these defendants and Wyeth-yerst Laboratory Company will be referred to collectively as "Wyeth" in this brief.

[2]*See* Plaintiffs' Brief, at p. 1 ("Whether or not [Section 2946(5)], and its provisions, are vise or unwise, is not the issue. Instead, the issue is whether the legislature chose a constitutional neans of accomplishing its end.")

II. DISCUSSION

A. PLAINTIFFS HAVE FAILED TO MEET THEIR HEAVY BURDEN TO ESTABLISH THAT SECTION 2946(5) IS UNCONSTITUTIONAL.

1. PLAINTIFFS HAVE NOT REBUTTED WYETH'S CENTRAL ARGUMENT THAT, IN ENACTING SECTION 2946(5), THE MICHIGAN LEGISLATURE EXERCISED, RATHER THAN DELEGATED, ITS LEGISLATIVE AUTHORITY.

As Wyeth stated in its Brief on Appeal, in enacting Section 2946(5), the Michigan Legislature did not delegate any of its legislative authority to anyone. Instead, the Michigan Legislature passed a law that provides that specific legal consequences under Michigan law will result from an act of independent significance, i.e., FDA's approval of a drug. Plaintiffs barely attempt to address this dispositive argument. Nor do they dispute the fact that Michigan courts have held that the practice of adopting factual determinations by non-legislative bodies to trigger statutory consequences is not a delegation, but an exercise, of legislative power.[3] Nor do Plaintiffs dispute that state courts throughout the country routinely have approved this common legislative practice and rejected similar "delegation" challenges.[4]

Rather than squarely confronting case law holding that legislatures are free to adopt determinations by agencies and private entities that have independent significance, Plaintiffs

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[3]For example, in Michigan Baptist Homes and Development Co v City of Ann Arbor, 55 Mich App 725, 737; 223 NW2d 324 (1974), *aff'd*, 396 Mich 660; 242 NW2d 749 (1976), the Court of Appeals upheld the constitutionality of a Michigan statute that made a state tax exemption to nonprofit corporations dependent on a determination by a federal agency. Similarly, in McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999), this Court upheld the constitutionality of a recently-enacted tort reform provision that adopts factual findings of non-legislative bodies in a manner indistinguishable from Section 2946(5). *See also* Council of Organizations & Others for Education About Parochiaid v Governor, 445 Mich 557, 586; 566 NW2d 208 (1997).

[4]*See, e.g.,* Lucas v Maine Comm'n of Pharmacy, 472 A2d 904 (Me 1984); State v Wakeen, 7 NW2d 364 (Wis 1953); Madrid v St Joseph Hospital, 928 P2d 250, 257 (NM 1996); Fulmer v Jensen, 379 NW2d 736, 740 (Neb 1986); In re Hansen, 275 NW2d 790, 796 (Minn 1978); Commissioner of Revenue v Massachusetts Mutual Life Ins Co, 384 Mass 607, 610; 428 NE2d 97 (1981); McHenry State Bank v Harris, 434 NE2d 1144, 1148 (Ill 1982). Plaintiffs have not distinguished or otherwise addressed any of these cases.

ıerely quote from the portion of the Court of Appeals' November 30, 2001 decision holding that ssimilation of standards having independent significance is proper only if such standards are ınchanging and then assert in a conclusory manner: "This Opinion is legally correct." *See* 'laintiffs' Brief, at pp. 27-28. However, the Court of Appeals' decision, most certainly, is not 'legally correct." Indeed, as discussed in Wyeth's Brief on Appeal, at pp. 19-22: (1) there is no 'alid basis for holding that the constitutionality of the Michigan Legislature's adoption of the ıctions of an external body as a trigger for statutory legal consequences depends on the courts' ɔerception of the relative permanence of the actions adopted; and (2) in holding that assimilation ɔf standards having independent significance is proper only if such standards are unchanging, the Court of Appeals misinterpreted Michigan Baptist Homes.[5] Plaintiffs have not challenged, and, herefore, effectively concede, these arguments.

2. THE FEW ARGUMENTS PRESENTED IN PLAINTIFFS' BRIEF AS TO THE CONSTITUTIONALITY OF SECTION 2946(5) LACK MERIT.

Plaintiffs devote just a few pages to addressing whether Section 2946(5) ınconstitutionally delegates legislative authority to the FDA. They repeatedly (and conclusorily) ıssert that the statute delegates legislative authority, but they never even attempt to articulate a heory on which this purported belief is based. *See, e.g.*, Plaintiffs' Brief, at pp. 20, 21, 24 and 26. Throughout Plaintiffs' Brief, Plaintiffs cite numerous cases that they say support their ırgument. But all of these cases are inapposite. For example, the cases cited in Plaintiffs' Brief, ıt pp. 20-26, merely establish a matter that is not in dispute, namely that, when there is a clear

[5]The Michigan Baptist Homes decision does not purport to suggest that there exists a nexus ɔetween the constitutionality of the assimilation of external findings and the constancy of decisions ısed by officials when making such findings. *See* Wyeth's Brief on Appeal, at pp. 19-22.

elegation, the legislature must provide sufficient standards to guide the agency or non-egislative body's decision-making. Those cases do not speak to the fundamental question resented here, which is, what constitutes a delegation? As discussed above and in Wyeth's Brief on Appeal, the pertinent authorities establish that the Michigan Legislature did not delegate ts legislative functions to anyone; it did not authorize the FDA to promulgate regulations, stablish policy, or make Michigan law.[6]

Plaintiffs attempt to find support in Buckman Co v Plaintiffs' Legal Committee, 531 US 341; 121 S Ct 1012 (2001) (discussing viability of state law fraud on the FDA claims), *see* Plaintiffs' Brief, at p. 6, but Buckman deals with preemption issues, not the delegation of egislative power. Moreover, Buckman is inapposite to this appeal because Plaintiffs did not llege fraud on the FDA or any comparable theory in these cases. Indeed, Plaintiffs stipulated or the purposes of Wyeth's summary disposition motions that **none** of the exceptions set forth in Section 2946(5) applied in their cases, *see* Exhibit A and Exhibit B. Therefore, the argument Plaintiffs now make as to Buckman is beside the point.[7] In any event, Plaintiffs' argument is ntenable because Section 2946(5) contains exceptions in addition to fraud on the FDA.

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[6]Plaintiffs also cite Knoke v Michelin Chemical Corp, 188 Mich App 456; 470 NW2d 420 (1991), in support of their contention that Section 2946(5) is unconstitutional. But, like all other cases cited by Plaintiffs, Knoke is wholly inapposite, inasmuch as it does not, directly or indirectly, address whether the Legislature may assimilate independently significant standards and determinations of public and private organizations such as the FDA into statutory law. Instead, Knoke simply holds that court rules promulgated by the Michigan Supreme Court may not be construed to vest mediation panels with judicial powers.

[7]*See, e.g.*, New York v Ferber, 458 US 747, 767-68 (1982) ("[t]he traditional rule is that a person to whom a statute may constitutionally be applied may not challenge that statute on the ground that it may conceivably be applied unconstitutionally to others in situations before the court"); Michigan Up & Out of Poverty Now Coalition v State, 210 Mich App 162, 170 (1995) (facial challenges to the constitutionality of legislation are generally disfavored); Department of Public Health v Tompkins, 34 Mich App 114, 118 (1971) (one cannot attack statute on ground that its application denies constitutional protection to others).

Finally, even if there were no exceptions available, the Michigan Legislature unquestionably had the power to eliminate **all** state liability for manufacturers and sellers of prescription drugs.[8]

In sum, all of the arguments put forth by Plaintiffs in support of their position that Section 2946(5) is unconstitutional are based on inapposite case law and a fundamental mischaracterization of the statute and what it effectuates.

3. PLAINTIFFS HAVE IGNORED WYETH'S NUMEROUS ARGUMENTS DEMONSTRATING THAT THE COURT OF APPEALS' DECISION-MAKING WAS DEEPLY FLAWED.

As stated in Wyeth's Brief on Appeal, in striking down Section 2946(5), the Court of Appeals made numerous errors in addition to its misinterpretation of Michigan Baptist Homes. Plaintiffs did not address any of Wyeth's arguments regarding the Court of Appeals' deeply flawed decision-making. Specifically, Plaintiffs ignored Wyeth's arguments that the Court of Appeals improperly: (1) relied heavily on two Michigan Supreme Court decisions, Coffman v State Board of Examiners in Optometry, 331 Mich 582; 50 NW2d 322 (1951), and Colony Town Club v Michigan Unemployment Comm'n, 301 Mich 107; 3 NW2d 28 (1942), that are either inapposite or **support** a finding that Section 2946(5) is constitutional;[9] (2) ruled that Section 2946(5) is a constitutionally suspect "reference statute" that incorporates into Michigan law a

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[8]Plaintiffs expressly concede this point: "The legislature has many ways in which it can ease the burden upon drug manufacturers, including the granting of out-and-out immunity to them, unconditioned upon anything." *See* Plaintiffs' Brief, at p. 26.

[9]In Plaintiffs' Brief, at pp. 19, 25, and 27, Plaintiffs say that Coffman mandates a finding that Section 2946(5) is unconstitutional. But Coffman supports Wyeth's position. In Coffman, the Michigan Supreme Court approved the use of a finding of independent significance by an external agency, namely the decision by a four-year college to graduate an applicant, as a prerequisite to the right to practice optometry. As discussed in Wyeth's Brief on Appeal, at pp. 26-27, the language from Coffman cited in Plaintiffs' Brief was not relevant to the issues before the Court and was untested *dictum* that is not binding authority, and is certainly not a proper basis for invalidating an act of the Michigan Legislature.

tandard from a different jurisdiction as the rule to be applied in Michigan courts;[10] (3) relied on ıe utter irrelevancy that the FDA is a federal agency;[11] and (4) failed to follow case law stablishing that courts may not second-guess the Legislature's determination that the FDA is vell equipped to make determinations about the safety of prescription drugs.[12]

Just as they ignored Wyeth's arguments as to the numerous errors contained in the Court ıf Appeals' decision, so too did Plaintiffs ignore other arguments underscoring the onstitutionality of Section 2946(6). Thus, Plaintiffs failed to even respond to Wyeth's ontention that: (1) declaring Section 2946(5) unconstitutional would destroy the well-accepted egislative practice of assimilating nationwide standards and findings, jeopardizing the onstitutionality of a wide range of similar Michigan statutes;[13] (2) if it had chosen to do so, the Michigan Legislature could have eliminated all liability for manufacturers and sellers of ırescription drugs, *see* McDougall, 461 Mich at 36; Shavers, 402 Mich at 620, yet Section

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[10]Moreover, the constitutional problem courts have identified with reference statutes, ıamely the difficulty of determining what standard to apply in Michigan courts if the underlying tandard is amended, is not present here. It is the fact of FDA approval at the time the drug is sold hat governs. That fact is never in doubt, and never changes.

[11]Unless there was a delegation – and there was none here – the fact that FDA is a federal ıgency has no bearing on the validity of the statute. This was the holding in Michigan Baptist Homes, as well as numerous cases decided by courts across the country that have upheld the onstitutionality of statutes that adopt factual findings made by federal agencies.

[12]See Shavers v Attorney General, 402 Mich 554, 614; 267 NW2d 72 (1974); Levy v Martin, 463 Mich 478; 620 NW2d 292 (2001); In re Certified Questions, 419 Mich 686, 691-92; 358 NW2d 873 (1984); In re Request for Advisory Opinion on Constitutionality of 1986 PA 281, 430 Mich 93, 109-10; 422 NW2d 186 (1988); Welton v Carriers Ins Co, 421 Mich 571, 580 n 4; 365 NW2d 170 (1984).

[13]In Plaintiffs' Brief, at p. 28, Plaintiffs baldly assert that, if it is allowed to stand, the Court ıf Appeals' decision in Taylor "will not lead to great destabilization, or massive nullification of tatutes" without even attempting to explain **why** they believe this is true. Wyeth respectfully ubmits that there is no principled way to insulate dozens of Michigan statutes, including the many ited in Wyeth's Brief on Appeal, from attack if the Court of Appeals ruling is upheld.

946(5) permits recoveries in certain appropriate circumstances; and (3) depriving the egislature of its ability to enact statutes like Section 2946(5) would destroy effective policy naking and deprive the Legislature of the benefits of federalism, whose essence is to allow the tates to profit from the "good ideas" of their sister states and federal government, see San Antonio Independent School Dist v Rodriguez, 411 US 1, 49-50; 93 S Ct 1278, 1304-05; 36 L Ed 2d 16 (1973). By ignoring these arguments, Plaintiffs have implicitly conceded that there is no answer to them.

C. IN CONTENDING THAT SECTION 2946(5) IS UNCONSTITUTIONAL, PLAINTIFFS MAKE INAPPROPRIATE POLICY ARGUMENTS AND IMPROPERLY QUESTION THE WISDOM OF THE MICHIGAN LEGISLATURE.

Plaintiffs' Brief is internally inconsistent. At page 1, they expressly acknowledge that, in letermining the constitutionality of Section 2946(5), this Court may not consider the wisdom of he policy underlying the statute: "Whether or not this act, and its provisions, are wise or nwise, is not the issue. Instead, the issue is whether the legislature chose a constitutional means of accomplishing its end." Nevertheless, Plaintiffs' Brief, fairly interpreted, has one primary purpose, namely to attack Section 2946(5) as both ill-advised and unfair. This assault, which, among other things, challenges the credibility and reliability of FDA findings as to drug safety, *see, e.g.,* Plaintiffs' Brief, at pp. 6, 10, 12-14, 20, is highly inappropriate for several reasons. First, and most fundamentally, as Plaintiffs expressly concede, their policy arguments are not relevant to the dispositive legal issue, namely whether Section 2946(5) unconstitutionally delegates legislative authority to the FDA. By focusing so extensively on "FDA-bashing" and other issues relating to the wisdom of Section 2946(5), Plaintiffs attempt to distract the Court from considering the legal merits of the arguments showing that the statute is constitutional.

Second, Plaintiffs' policy-related arguments are based on misrepresentations and otherwise lack substantive merit. As demonstrated in Wyeth's Brief on Appeal, as well as the Amicus Curiae Brief of the Product Liability Advisory Council, Inc. in Support of Defendants-Appellants' Appeal dated August 22, 2002, App, 140a-149a, Plaintiffs' skewed portrayal of the FDA and its drug approval process is inaccurate and is based on manifestly biased and outdated newspaper stories. By contrast, it is undisputed that the FDA is recognized as the leading regulatory agency of pharmaceuticals in the world, and no court in this case has suggested that it was somehow irrational for the Michigan Legislature to have relied on the comprehensive regulatory scheme requiring pharmaceutical manufacturers to prove the safety and effectiveness of their drug products.[14]

Plaintiffs' additional challenges to the fairness of Section 2946(5) are similarly unavailing. Plaintiffs suggest that several thousand Michigan residents who ingested the prescription drugs at issue will become "tax burdens" if Section 2946(5) is deemed constitutional and that the statute has deprived Michigan residents, but not residents of other states, of the opportunity to participate in Wyeth's nationwide class action settlement. Tax consequences are, of course, not even remotely relevant to the delegation issue. Moreover, Michigan residents have **not** been excluded from the nationwide settlement and Plaintiffs' factual assertion to the contrary is a blatant falsehood. Plaintiffs' law firm, Charfoos & Christensen, P.C., has

[14]Furthermore, Plaintiffs' notion that the "tort reform" law is somehow illegitimate because it has not been enacted elsewhere is squarely at odds with the essence of federalism, *see* Marshall v Consumers Power Co, 65 Mich App 237, 263; 237 NW2d 266 (1976) ("States may adopt different solutions to their own needs and, in that way, become 'experimental laboratories.'"), and the views of leading academicians and legal commentators. *See* Brief of Amicus Curiae of Pharmaceutical Research and Manufacturers of America, at p. 2, App, 136a (noting that the American Law Institute and others have urged for years that FDA approval be deemed an absolute defense).

epresented numerous Michigan residents who have registered for, and/or received benefits ursuant to, the nationwide settlement.[15]

Finally, Plaintiffs' objection that Michigan residents cannot pursue claims regarding rugs whose FDA approval has been withdrawn is unfounded. As explained in Wyeth's Brief on ppeal, at p. 36, legislatures commonly draw "bright lines" and, in this instance, the Michigan egislature reasonably determined that a "bright line" that allows drug manufacturers to rely on he fact of FDA approval in marketing drugs would improve the overall fairness of product iability law. Moreover, Section 2946(5) is not immutable, as Plaintiffs' claim; the Michigan egislature always has the power to repeal or modify the statute to the extent it is, for any reason, aid to be unfair.

In sum, Plaintiffs' effort to transform this case into a referendum on the wisdom of the Michigan Legislature's enacting Section 2946(5) cannot succeed. Not only is this issue rrelevant to a determination as to the constitutionality of Section 2946(5), but Plaintiffs' riticisms of the statute are ill-conceived or based on misrepresentations.

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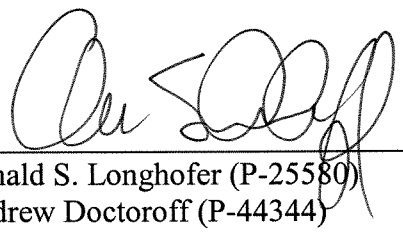
[15]By way of example, the plaintiffs in the following cases represented by the Charfoos firm opted to participate in the settlement after initiating lawsuits in various state courts in Michigan: (1) Carlon v Dempsey, Ottawa County Circuit Court, Docket No. 00-35864; (2) Elwert v Saunders, Oakland County Circuit Court, Docket No. 99-017303; (3) Keeler v Borenitsch, Manistee County Circuit Court, Docket No. 99-9694; (4) Reiter v Moracewskis, Macomb County Circuit Court, Docket No. 99-4655; (5) Wirth v Cooper, Jackson County Circuit Court, Docket No. 99-97104; (6) Trebnik v Kpadenen, Oakland County Circuit Court, Docket No. 99-017837; (7) Aldini v Smithkine, Wayne County Circuit Court, Docket No. 00-002568; and (8) Campbell v Pierce, Muskegon County Circuit Court, No. 99-39784. Thousands of other Michigan residents also have decided to participate in the nationwide settlement with Wyeth.

III. CONCLUSION

Plaintiffs do not address, and thereby implicitly concede, the primary dispositive rguments establishing that the Michigan Legislature did not delegate legislative authority to the DA, but instead exercised its power to make Michigan law by incorporating findings with ndependent significance. Further, the few legal arguments Plaintiffs do advance fail to refute he case law and other authority demonstrating that the Court of Appeals' holding must be eversed. Plaintiffs simply cannot meet their heavy burden to establish that Section 2946(5) is nconstitutional by second-guessing the wisdom of the Michigan Legislature's decision to enact he statute. In sum, Plaintiffs' arguments are substantively lacking, and only serve to underscore hat the Court should reverse the Court of Appeals' decision, declare Section 2946(5) to be onstitutional, and hold that Plaintiffs' claims are barred by the statute.

Respectfully submitted,
HONIGMAN MILLER SCHWARTZ AND COHN

By: 

Ronald S. Longhofer (P-25580)
Andrew Doctoroff (P-44344)
2290 First National Building
Detroit, Michigan 48226-3583
(313) 465-7360

SECREST, WARDLE, LYNCH, HAMPTON
TRUEX AND MORLEY
John Mitchell (P-39892)
Michael L. Updike (P-28964)
Attorneys for Defendants-Appellants
30903 Northwestern Highway
P.O. Box 3040
Farmington Hills, Michigan 48333-3040
(248) 851-9500

ARNOLD & PORTER
Donald O. Beers
Darryl W. Jackson
Michael C. Augustini
555 Twelfth Street, N.W.
Washington, DC 20004-1202
(202) 942-5000

Attorneys for Defendants-Appellants A.H. Robins Company, Incorporated, Wyeth-Ayerst Laboratories Company and American Home Products Corporation

)ated: November 19, 2002

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EXHIBIT A

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STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WAYNE

TAMARA TAYLOR and
LE ANNE RINTZ, on behalf
of themselves and all others
similarly situated,

Plaintiffs

v.

No. 97-731636-NP
Hon. Marianne O. Battani

GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, ZENITH GOLDLINE PHARMACEUTICALS, INC., ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICAL COMPANY, INC., ION LABORATORIES, INC., MEDEVA PHARMACEUTICALS, INC., A.H. ROBINS COMPANY, INCORPORATED, WYETH-AYERST LABORATORIES COMPANY, AMERICAN HOME PRODUCTS CORPORATION, INTERNEURON PHARMACEUTICALS, INC., CAMALL COMPANY, LABORATOIRES SERVIER and ALL MICHIGAN PHYSICIANS WHO PRESCRIBED OR GAVE FEN-PHEN AND/OR REDUX TO MICHIGAN PATIENTS,

Defendants

SAMUEL L. SIMPSON (P20515)
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

JAMES F. KAMP (P36651)
Attorney for Gate Pharmaceuticals
11th Floor Buhl Building
Detroit, MI 48226
(313) 962-0643

THOMAS J. FOLEY (P31111)
Attorney for Smithkline Beecham
One Woodward Avenue, 10th Floor
Detroit, MI 48226
(313) 965-7526

STEVEN M. HICKEY (P33142)
Attorney for Zenith Goldline/
Richwood Pharmaceuticals
400 Renaissance Ctr., Suite 1010
Detroit, MI 48243
(313) 396-4600

DANIEL J. McCARTHY (P26882)
Attorney for Abana Pharmaceuticals
2301 W. Big Beaver Road, Suite 500
Troy, MI 48084
(248) 649-1330

GARY SHARP (P41554)
Attorney for ION Labs
6905 Telegraph Road, Suite 114
Bloomfield Hills, MI 48301
(248) 540-9636

WILLIAM D. BOOTH (P10999)
Attorney for Medeva Pharmaceuticals
505 North Woodward, Suite 3000
Bloomfield Hills, MI 48303
(248) 901-4017

JOHN MITCHELL (P39892)
Attorney for A.H. Robins Company/
Wyeth-Ayerst Laboratories/
American Home Products Corp.
30903 Northwestern Highway
P.O. Box 3040
Farmington Hills, MI 48333-3040
(248) 539-2839

STEVE J. WEISS (P32174)
Attorney for Interneuron Pharmaceut.
1760 S. Telegraph Road, Suite 300
Bloomfield Hills, MI 48302
(248) 335-5000

MARK F. MILLER (P36404)
Attorney for Camall Company
800 Buhl Building
Detroit, MI 48226
(313) 963-9050

RESPONSE TO DEFENDANT'S MOTION FOR SUMMARY DISPOSITION

Plaintiffs, Tamara Taylor and Lee Anne Rintz, on behalf of themselves and all others similarly situated, through their attorneys, **Charfoos & Christensen, P.C.**, request that this Honorable Court deny defendant's motion for summary disposition. In further response to numbered paragraphs in defendant's motion, plaintiffs state as follows:

1. Plaintiffs agree that this complaint state a product liability action against manufacturers and sellers of drug products, namely, Redux and Fen-Phen. Although both drugs were initially approved by the United States Food & Drug Administration, they were later withdrawn as unsafe.

2. Plaintiffs agree that the drugs were labeled in compliance with the Food & Drug Administration's guidlines. Plaintiffs contend for the reasons set out herein that MCL 600.2946(5) is unconstitutional, for the reasons set out in the accompanying brief.

3. Plaintiffs agree that no statutory exceptions have been pled. However, plaintiffs do contest the applicability of the statute, inasmuch as the statute is unconstitutional for the reasons set out in the accompanying brief.

4. Although plaintiffs bring the motion under MCR 2.116(C)(8), plaintiffs, when challenging the constitutionality of the statute, may submit to this court necessary background information on why the statute is unconstitutional. Plaintiffs have done so, in the accompanying brief.

Therefore, plaintiffs respectfully request that this Honorable Court deny defendant's motion for summary disposition on the basis of

the unconstitutionality of MCLA 600.2946(5). Furthermore, because MCL 600.2946(5) is part of a non-severable "tort reform" package, plaintiffs request that this Honorable Court strike the entire act as unconstitutional for the reasons set out herein.

CHARFOOS & CHRISTENSEN, P.C.

By _____
J. DOUGLAS PETERS (P25686
SAMUEL L. SIMPSON (P20515)
DAVID R. PARKER (P39024)
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

Dated: May 29, 1998

EXHIBIT B

STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF WASHTENAW

JUDITH H. ROBARDS and
KENNETH W. ROBARDS,

Plaintiffs,

Case No. 99-5373-NM

-vs-

Hon. David S. Swartz

JOYCE E. KAFERLE, M.D., EVELYN ECCLES, M.D., and GATE PHARMACEUTICALS, SMITHKLINE BEECHAM CORPORATION, ZENITH GOLDLINE PHARMACEUTICALS, INC., ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICAL COMPANY, INC., ION LABORATORIES, INC., MEDEVA PHARMACEUTICALS, INC., A. H. ROBBINS COMPANY, AMERICAN HOME PRODUCTS CORPORATION, WYETH LABORATORIES, INC. PARMED PHARMACEUTICALS, INC., EON LABS MANUFACTURING, INC., and LES LABORATOIRES SERVIER, all foreign corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080
Fax: 313-875-8522

William D. Booth (P10999)
PLUNKETT & COONEY, P.C.
Attorneys for Medeva Pharmaceuticals
505 N. Woodward, Suite 3000
Bloomfield Hills, MI 48304
(248) 901-4067
Fax: 248-901-4040

John Mitchell (P39892)
Attorneys for A. H. Robins, Wyeth-Ayerst and American Home Products
30903 Northwestern Highway
P. O. Box 3040
Farmington Hills, MI 48333-3040
(248) 539-2827
Fax: (248) 851-2158

Ronald F. Graham (P25925)
Attorney for Gate Pharmaceuticals
505 N. Woodward, Suite 1000
Bloomfield Hills, MI 48304
(248) 642-7880
Fax: (248) 642-9319

Thomas J. Foley (P31111)
Ellen C. Padesky (P51484)
Attorneys for Smithkline Beecham
One Woodward, Tenth Floor
Attorneys for Smithkline Beecham
Detroit, MI 48226
(313) 965-7526
Fax: (313) 965-7403

Gary Sharp (P41554)
Attorney for ION Labs, Zenith Goldline and Richwood
6905 Telegraph Road, #114
Bloomfield Hills, MI 48301
(248) 540-9636
Fax: (248) 540-9639

Daniel J. McCarthy (P26882)
Attorney for Abana
2301 W. Big Beaver, Suite 500
Troy, MI 48084
(248) 649-1330
Fax: (248) 649-1622

Steven M. Hickey (P33142)
Attorney for EON and ParMed Pharmaceuticals
400 Renaissance Center #1010
Detroit, MI 48243
(313) 396-4600
Fax: (313) 396-4601

Stephen D. McGraw (P26568)
Attorney for Defendant Doctors
500 Woodward Avenue, Suite 2500
Detroit, MI 48226-3406
(313) 961-0200
Fax: (313) 961-0388

RESPONSE TO DEFENDANT'S MOTION FOR SUMMARY DISPOSITION

Plaintiffs, Judith Robards and Kenneth Robards, through their attorneys, Charfoos & Christensen, P.C., request that this Honorable Court deny defendant's motion for summary disposition. In further response to numbered paragraphs in defendant's motion, plaintiffs state as follows:

1. Plaintiffs agree that this complaint state a product liability action against manufacturers and sellers of drug products, namely, Redux and Fen-Phen. Although both drugs were initially approved by the United States Food & Drug

Administration, they were later withdrawn as unsafe.

2. Plaintiffs agree that the drugs were labeled in compliance with the Food & Drug Administration's guidelines. Plaintiffs contend for the reasons set out herein that MCL 600.2946(5) is unconstitutional, for the reasons set out in the accompanying brief.

3. Plaintiffs agree that no statutory exceptions have been pled. However, plaintiffs do contest the applicability of the statute, inasmuch as the statute is unconstitutional for the reasons set out in the accompanying brief.

4. Although plaintiffs bring the motion under MCR 2.116(C)(8), plaintiffs, when challenging the constitutionality of the statute, may submit to this court necessary background information on why the statute is unconstitutional. Plaintiffs have done so, in the accompanying brief.

Therefore, plaintiffs respectfully request that this Honorable Court deny defendant's motion for summary disposition on the basis of the unconstitutionality of MCLA 600.2946(5).

CHARFOOS & CHRISTENSEN, P.C.

By _____

J. DOUGLAS PETERS (P25686
SAMUEL L. SIMPSON (P20515)
DAVID R. PARKER (P39024)
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

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